

REMARKS

Claims 7 and 32 are currently pending in this application. Claim 7 is amended. No new matter has been introduced. Reconsideration of the pending claims in view of the arguments/comments below is earnestly requested.

Rejections under 35 U.S.C. § 102

Claims 7 and 32 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,828,093 to Elledge et al. for reasons stated on page 3 of the Office Action.

For anticipation under 35 U.S.C. §102, the reference “must teach every aspect of the claimed invention either explicitly or impliedly. Any feature not directly taught must be inherently present.” (MPEP §706.02). “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” Verdegaal Bros. v. Union Oil Co. of California, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Independent Claim 7, as amended, is directed to a composition comprising: a vector for capture, cloning, manipulation, production and delivery of large nucleic acids to a target cell comprising: (a) a first arm having a first selectable marker, a first cyclization element, and a first segment homologous to the 5' terminus of a target polynucleotide; and (b) a second arm having a second selectable marker, a second cyclization element, and a second segment homologous to the 3' terminus of the target polynucleotide, wherein the vector comprises a sequence for homologous recombination with the target polynucleotide in yeast, and wherein the target polynucleotide is a

polynucleotide of a virus, and said virus is selected from the group consisting of adenovirus, adeno-associated virus, pox virus, papova virus and herpes virus.

Elledge generally describes vectors and methods for rapid subcloning *in vivo* and *in vitro*. Briefly, Elledge describes a technique of using an univector construct, which contains a gene of interest and a sequence-specific recombinase target site, to transfer the gene of interest into an expression vector, which contains a sequence-specific recombinase target site located downstream of a regulatory element, in the presence of a recombinase. The end product is an combined expression construct having the gene of interest of the univector under the regulation of the regulatory element of the expression vector.

As shown in Figures 1, 12, 14, 20 and 24 of Elledge, only the final product of the process, i.e., the combined expression construct, contains two selectable markers and two cyclization elements. Elledge does not describe a combined expression construct that comprises a sequence for homologous recombination with a target polynucleotide in yeast. The gist of the invention described in Elledge et al. is rapid cloning of a gene of interest into a vector having a desired regulatory element utilizing sequence-specific recombinase technology. Thus, there is no need to further manipulate the expression construct after the integration of the gene of interest into the expression vector.

The Examiner alleges that the gene of interest can be DNA from an adeno-associated virus (AAV). Applicants respectfully submit that the simple existence of an AAV gene in the expression construct of Elledge does not equate to description for “a first segment homologous to the 5' terminus of a target polynucleotide” and “a second segment homologous to the 3' terminus of the target polynucleotide,” with the target

polynucleotide being a polynucleotide from AAV. Additionally, there is no mention in Elledge that the expression vector is capable of homologous recombination with the target polynucleotide in yeast. Thus Elledge not only lacks explicit description of the invention as required for anticipation under 35 U.S.C. § 102(e), Elledge also fails to teach or suggest a vector that is capable of homologous recombination with a target polynucleotide in yeast.

Accordingly, Applicants respectfully submit that Elledge does not anticipate, Claim 7 or claims dependent thereon. Withdrawal of the rejection under 35 U.S.C. § 102(e) is respectfully requested.

Rejections under 35 U.S.C. § 103

Claims 7 and 32 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,348,886 to Lee, et al. (hereinafter “Lee”) for reasons stated on pages 4-6 of the Office Action.

To establish a *prima facie* case of obviousness the prior art reference (or references when combined) must teach or suggest all of the claim limitations. In re Vaeck, 20 USPQ2d 1438 (Fed. Cir. 1991) and MPEP § 2142. Moreover, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art (see MPEP 2143.01; In re Fine, 5 USPQ2d 1596 (Fed. Cir. 1988); In re Jones, 21 USPQ2d 1941 (Fed. Cir. 1992)).

Lee generally describes a method for producing infectious recombinant baculoviruses in bacteria. Lee does not teach or suggest a vector that is capable of homologous recombination with a target polynucleotide in yeast. Elledge does not cure the deficiency of Lee. As discussed above, Elledge also does not teach or suggest a vector that is capable of homologous recombination with a target polynucleotide in yeast. Accordingly, Applicants respectfully submit that Lee and Elledge, individually or in combination, do not render Claim 7 of the instant invention obvious.

If an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious. In re Fine, 5 USPQ2d 1596 (Fed Cir. 1988). Withdrawal of the 35 U.S.C. § 103 rejection of Claims 7 and 32 is respectfully requested.

CONCLUSION

In view of the foregoing remarks, favorable reconsideration of all pending claims is requested. Applicants respectfully submit that this application is in condition for allowance and requests that a notice of allowance be issued. If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to contact Applicants' counsel, Linda Judge at (415) 836-2586.

Respectfully submitted,

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